

# EXHIBIT 19



Re: URGENT !!!!  
Daniel Sessler  
to:  
ghansen  
08/31/2012 09:41 AM  
Hide Details  
From: Daniel Sessler <ds@or.org>

To: ghansen@mmm.com

Gary,

I'm pretty unhappy. I took this project on as a favor and it has ended up costing a huge amount of time -- and now more to come. Furthermore, this may damage my reputation; just the fact that a complaint was filed already has to some extent.

This was completely preventable. As I've been saying for a year, only a bacterial sampling study will adequately deal with this issue. If we had those data now -- as we should have -- that would be the full and complete answer to Scotts accusations.

I'm underwhelming with the way Arizant/3M is being managed. It has taken forever to get the analysis for DTT. As a result, you're going into your big launch without a validation paper even submitted, much less in press. It should have been long-since accepted. There has been no progress on doing a DTT study in the relevant (non-cardiac) population. And the decision not to do bacterial sampling was just short-sighted; there is no way to put any gloss on that. Frankly, my enthusiasm for continuing with 3M is modest at this point...

Regards, Dan.  
216-870-2620

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On Aug 31, 2012, at 10:15 AM, [ghansen@mmm.com](mailto:ghansen@mmm.com) wrote:

There is much to say, and I've already worked through most of it. Let me pull it together.

Gary

<Mail Attachment.gif>

Gary Hansen, Ph.D. | Director of Research and Development  
Arizant Healthcare Inc., a 3M company  
Patient Warming Business, 10393 West 70th Street | Eden Prairie, MN 55344  
Office: 952 947 1388 | Mobile: 952 200 5645  
ghansen@mmm.com | www.3M.com

From: Daniel Sessler <[ds@or.org](mailto:ds@or.org)>  
To: Hansen Gary <[ghansen@mmm.com](mailto:ghansen@mmm.com)>, Van Duren Al <[apvanduren@mmm.com](mailto:apvanduren@mmm.com)>, Olmsted Russell <[aes99@att.net](mailto:aes99@att.net)>, Kuelpmann Ruediger <[ruediger.kuelpmann@hslu.ch](mailto:ruediger.kuelpmann@hslu.ch)>  
Date: 08/31/2012 08:48 AM  
Subject: URGENT !!!!

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Hi Folks,

We have a problem, in the form of an official complaint, obviously from Scott Augustine, about the laminar flow paper. Steve wants to discuss the issue with me Sunday and I need to have a full and convincing response ready. Unfortunately, this topic is well outside my area of expertise so I'm going to need your help. I'd be grateful if you would provide detailed, factual, and referenced responses for each of the technical issues.

I suppose I should point out the obvious. For a year I've been saying that the only way to put this issue to bed is to do a clinical bacterial sampling study. We should have had those results by now -- which would fully address the issue. As is, we're again playing catch up. It was a foolish decision not to do that study long ago.

Gary, call me when you can: 216-870-2620.

Regards, Dan.

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Begin forwarded message:

**From:** "Steven Shafer" <[steven.shafer@stanford.edu](mailto:steven.shafer@stanford.edu)>  
**Subject:** Question regarding forced air warming study  
**Date:** August 31, 2012 9:15:20 AM EDT  
**To:** "Daniel Sessler" <[ds@or.org](mailto:ds@or.org)>

Dear Dan:

We have received a credible report suggesting that your recent paper in Anesthesia & Analgesia misrepresents the safety of forced air warming. The article in question is attached.

The complaint we have received is quite detailed. To quickly summarize the key points:

1. The "standard" test procedures were not designed to test forced air warming devices.
2. Your study omitted two of the standard test procedures.
3. Your study omitted the second part of the standard test procedure used in the study.
4. You modified the standard procedures so that the results would support his device.
5. Your conclusion that forced air warming devices are safe in all circumstances is unsupported by the facts. You state "Forced air warming does not degrade laminar flow performance or reduce operating room air quality." The conclusion should be limited to the exact circumstances of the test that was conducted.
6. You did not measure the effects of rising waste heat from forced air warming devices.
7. You studied the device in an artificial setting where the rising waste heat phenomenon was least likely to be detectable over the surgical site – restricting the heat to the head end of the patient.
8. Your study is contradicted by 4 recent papers:
  - Belani et al. Patient warming excess heat: Effects on Orthopedic Operating Room Ventilation Performance. *Anesthesia & Analgesia*. 2012;
  - McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. *Journal of Bone and Joint Surgery-Br (JBJS-Br)* 2011;93:1537-1544.
  - Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *JBJS-Br.* 2012;94-B:254-6.
  - Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012;67:244-249.

Several editors have looked at the paper in question, and it does appear that the paper does not follow the standard that it claims to follow. Specifically, you claim to have followed Annex C of the DIN standard. This Annex requires a two-part test. It appears from your paper that you only conducted one of the two parts.

There is also concern about the placement of the surrogate surgeons. In your study, they are placed side-by-side and pressed against the side of the surgical table. The DIN standard calls for a 20cm space between the tubes. Thus, your study appears to have not followed the DIN standard. More significantly, has your placement of the surrogate surgeons impeded the ingress of waste heat or contaminating particles from the sides of the table toward the sampling probe?

As mentioned, the position of the heat source similarly appears to not comply with the requirements of the DIN standard.

The author of the complaint suggests intentional deceit, suggesting you created a test that forced air warming would pass, knowing it would fail a test that fully adhered to the DIN standard. I do not find the concerns about your intentions credible. Thus, your intentions are not in question. The question before us is entirely scientific: is your study description accurate (e.g., the statement that it complies with an accepted standard), and are your conclusions fully supported by your findings?

I have had a rather challenging schedule this summer, complicated by my wife's recent illness, my transfer from Columbia University to Stanford University (my new contact information is below), launching two step children into college, and handling issues with my wife's house in New Jersey. For example, I spent yesterday at Scripps college in Southern California helping my step-daughter move in as a freshman. Today I'm clinical at Stanford. Tomorrow I fly to New Jersey to pack up the house for the movers, who are arriving on

Tuesday. My whole summer has been like this. An unfortunate consequence is that I've let these concerns languish so I could keep up with the manuscript flow. As a result, there is now a little time pressure to see that these concerns are addressed.

Is there any chance of our discussing these concerns by phone on Sunday?

I appreciate your consideration, and look forward to seeking a scientifically grounded resolution of these issues.

Sincerely,

Steve

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Steven L. Shafer, MD

Editor-in-Chief, *Anesthesia & Analgesia*

Professor of Anesthesia, Stanford University

Adjunct Professor of Bioengineering and Therapeutic Sciences, UCSF

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[attachment "Anesth Analg-2011-Sessler-1416-21.pdf" deleted by Gary Hansen/US-Corp03/3M/US]